

I Claim:

1. A method for detecting human kallikrein 13 associated with endocrine cancer in a patient comprising:
 - (a) taking a sample derived from a patient;
 - (b) detecting in the sample kallikrein 13; and
 - (c) comparing the detected amount with an amount detected for a standard.
2. A method for diagnosing and monitoring endocrine carcinoma in a subject comprising detecting kallikrein 13 in a sample from the subject.
3. A method as claimed in claim 1 or 2 wherein the kallikrein 13 is detected using antibodies specifically reactive with kallikrein 13 or a part thereof.
4. A method of detecting endocrine cancer in a patient, the method comprising comparing:
 - (a) levels of kallikrein 13 in a sample from the patient; and
 - (b) normal levels of expression of a kallikrein 13 in a control sample, wherein a significant difference in levels of kallikrein 13, relative to the corresponding normal levels, is indicative of endocrine cancer.
5. A method for screening a subject for endocrine cancer comprising:
 - (a) obtaining a biological sample from a subject;
 - (b) detecting the amount of kallikrein 13 in said sample; and
 - (c) comparing said amount of kallikrein 13 detected to a predetermined standard, where detection of a level of kallikrein 13 that is significantly different than that of a standard is indicative of endocrine cancer.
6. A method of assessing whether a patient is afflicted with or has a pre-disposition for endocrine cancer, the method comprising comparing:
 - (a) levels of kallikrein 13 in a sample from the patient; and
 - (b) normal levels of kallikrein 13, in samples of the same type obtained from control patients not afflicted with endocrine cancer, wherein significantly different levels of kallikrein 13, relative to the corresponding normal levels of the kallikrein 13, is an indication that the patient is afflicted with endocrine cancer.
7. A method for monitoring the progression of endocrine cancer in a patient, the method comprising:
 - (a) detecting in a sample from the patient at a first time point, kallikrein 13;
 - (b) repeating step (a) at a subsequent point in time; and
 - (c) comparing levels detected in steps (a) and (b), and thereby monitoring the progression of endocrine cancer.
8. A method for screening a subject for endocrine cancer comprising:
 - (a) incubating a biological sample from the subject with a first antibody specific for kallikrein 13 which is directly or indirectly labeled with a detectable substance, and a second antibody specific for kallikrein 13 which is immobilized;
 - (b) detecting the detectable substance thereby quantitating kallikrein 13 in the biological sample; and

(c) comparing the quantitated kallikrein 13 with levels for a predetermined standard.

9. A method for determining the prognosis of an individual with ovarian cancer comprising:

- contacting an amount of an antibody which binds to a kallikrein 13 protein, with a sample from the patient so as to form a complex comprising the antibody and kallikrein 13 protein in the sample;
- determining or detecting the presence or amount of complex formation in the sample;
- comparing the amount of kallikrein 13 present in the sample with the amount of kallikrein 13 in a control, wherein a higher amount of kallikrein 13 in the sample compared with the amount in the control is indicative of a favourable prognosis, in particular, early stage disease, no residual tumor, optimal debulking success, longer PFS and/or OS.

10. A method of any preceding claim which further comprises detecting one or more of human stratum corneum chymotryptic enzyme (HSCCE), haptoglobin alpha, osteopontin, kallikrein 2, kallikrein 3, kallikrein 4, kallikrein 5, kallikrein 6, kallikrein 8, kallikrein 10, kallikrein 11, kallikrein 14, kallikrein 15, CA125, CA15-3, CA19-9, OVX1, lysophosphatidic acid (LPA) or carcinoembryonic antigen (CEA).

11. A method for assessing the potential efficacy of a test agent for inhibiting endocrine cancer in a patient, the method comprising comparing: (a) levels of kallikrein 13 in a first sample obtained from a patient and exposed to the test agent; and (b) levels of kallikrein 13 in a second sample obtained from the patient, wherein the sample is not exposed to the test agent, wherein a significant difference in the levels of expression of kallikrein 13 in the first sample, relative to the second sample, is an indication that the test agent is potentially efficacious for inhibiting endocrine cancer in the patient.

20. A method of assessing the efficacy of a therapy for inhibiting endocrine cancer in a patient, the method comprising comparing:

- levels of kallikrein 13 in a first sample obtained from the patient, and
- levels of kallikrein 13 in a second sample obtained from the patient following therapy, wherein a significant difference in the levels of expression of kallikrein 13 in the second sample, relative to the first sample, is an indication that the therapy is efficacious for inhibiting endocrine cancer in the patient.

25. 13. A method of selecting an agent for inhibiting endocrine cancer in a patient the method comprising:

- obtaining a sample of cells affected by endocrine cancer from the patient;
- separately exposing aliquots of the sample in the presence of a plurality of test agents;
- comparing levels of kallikrein 13 in each of the aliquots; and
- selecting one of the test agents which alters the levels of kallikrein 13 in the aliquot containing that test agent, relative to other test agents.

30. 14. A method of inhibiting endocrine cancer in a patient, the method comprising:

- obtaining a sample comprising cells affected by endocrine cancer from the patient;
- separately maintaining aliquots of the sample in the presence of a plurality of test agents;
- comparing levels of kallikrein 13 in each of the aliquots; and

(d) administering to the patient at least one of the test agents which alters the levels of kallikrein 13 in the aliquot containing that test agent, relative to other test agents.

15. A method of assessing the potential of a test compound to contribute to endocrine cancer, the method comprising:

5 (a) maintaining separate aliquots of cells affected by the endocrine cancer in the presence and absence of the test compound; and

(b) comparing expression of kallikrein 13 in each of the aliquots, and wherein a significant difference in levels of kallikrein 13 in the aliquot maintained in the presence of the test compound, relative to the aliquot maintained in the absence of the test compound, is an indication that the test compound possesses potential to contribute to endocrine cancer.

10 16. A method for imaging a endocrine cancer tissue comprising administering to a tissue of a subject with endocrine cancer imaging agents that carry imaging labels and are capable of targeting or binding to kallikrein 13, and optionally other endocrine cancer markers, in the tissue.

17. An *in vivo* method for imaging endocrine cancer comprising:

15 (a) injecting a patient with an imaging agent that binds to kallikrein 13, the imaging agent carrying a label for imaging the cancer;

(b) allowing the imaging agent to incubate *in vivo* and bind to kallikrein 13 associated with the cancer; and

(c) detecting the presence of the label localized to the cancer.

20 18. A method as claimed in claim 17 wherein the imaging agent is an antibody which recognizes kallikrein 13.

19. A method as claimed in claim 17 wherein the label is a radiolabel, fluorescent label, nuclear magnetic resonance active label, positron emitting isotope detectable by a positron emission tomography ("PET") scanner, chemiluminescer, or enzymatic marker.

25 20. A kit for carrying out a method as claimed in any preceding claim.

21. A kit for assessing whether a patient is afflicted with endocrine cancer, the kit comprising reagents that specifically bind with kallikrein 13.

22. A kit for assessing the suitability of each of a plurality of agents for inhibiting endocrine cancer in a patient, the kit comprising:

30 (a) the plurality of agents; and

(b) reagents for detecting kallikrein 13.

23. A kit as claimed in claim 21 or 22 wherein the reagents are antibodies that specifically bind with protein or protein fragments corresponding to kallikrein 13.